FDA-Industry BsUFA II Reauthorization Negotiation Meeting
Finance Sub-group
May 26, 2016, 1:00pm-2:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

The purpose of the meeting was to discuss proposed statutory language for BsUFA II financial enhancements.

Participants

FDA		Industry	
Mark Ascione	CDER	Sascha Haverfield	PhRMA
Josh Barton	CDER	Mark Hendrickson	GPhA Biosimilars Council
Yanming Chae	CBER	Kay Holcombe	BIO
Joseph Franklin	OC	Stacy Holdsworth	PhRMA (Eli Lilly)
Azada Hafiz	CDER	Bruce Leicher	GPhA Biosimilar Council (Momenta)
Andrew Kish	CDER	Michael Levy	PhRMA
Kirk Kerr	CDER	David Gaugh	GPhA Biosimilars Council
Robert Marcarelli	OC	John Pakulski	GPhA Biosimilars Council (Mylan)
Amanda Roache	CDER	Michael Werner	Biosimilars Forum (Holland & Knight)
		Andrew Emmett	PhRMA (Pfizer)

BsUFA II Statutory Language

FDA and industry continued discussion of additional edits to the proposed revisions to the fee provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the justifications for the proposed statutory changes. FDA and industry identified a small number of minor technical edits to the documents to enhance clarity. Contingent on these further edits, FDA and industry agreed the draft documents reflect the proposed BsUFA II changes to the current fee structure and were ready for review by the Steering Committee.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.